UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION NO. 01-CV-12257-PBS
	)	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO ALL ACTIONS	)	

ASTRAZENECA PHARMACEUTICALS LP'S INDIVIDUAL MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT ON THE CLASS 1 AND CLASS 2 CLAIMS UNDER MASSACHUSETTS GEN. LAWS CH. 93A

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PRELIMINARY STATEMENT

Plaintiffs' Motion for Summary Judgment Against All Track 1 Defendants and the Track 1 Defendants' Joint Motion for Summary Judgment demonstrate that the parties agree on a core threshold legal issue in this case: the Class 1 and Class 2 claims against the Track 1 Defendants depend on whether Plaintiffs are correct that the term "average wholesale price" in the Medicare Part B regulation and statute should be construed to mean "average sales price." As demonstrated in the Track 1 Defendants' Joint Memorandum of Law in Support of Motion for Summary Judgment, and discussed further below, Plaintiffs' proposed interpretation of AWP does not result from, and is contrary to, established principles of statutory construction. Plaintiffs' Motion for Summary Judgment should be denied and summary judgment should be granted in favor of AstraZeneca.[1]

COUNTER-STATEMENT REGARDING PLAINTIFFS' STATEMENT OF FACTS[2]

Plaintiffs' motion rests on their own nefarious characterization of the record, which is plainly in dispute, as demonstrated in AstraZeneca's Counter Statement to Plaintiffs' L.R. 56.1 Statement, and a fundamental misconstruction of the term AWP. The fundamental premise of Plaintiffs' summary judgment argument is that AWP should reflect an actual "average sales price." Because it did not, they argue that AstraZeneca "manipulated" the AWP of Zoladex.

[1] AstraZeneca objects to Plaintiffs' inclusion of AstraZeneca PLC, Zeneca Inc. and "AstraZeneca U.S." in their definition of "AstraZeneca." AstraZeneca Pharmaceuticals LP is the only defendant in this action. Zeneca Inc. has never been served; AstraZeneca PLC is not named as a defendant in the Fourth Amended Master Consolidated Class Action Complaint; and "AstraZeneca U.S." does not even exist.

[2] Plaintiffs failed to support their Local Rule 56.1 statement with citations to the record as required by local rule, and their motion could be denied on this ground alone. GE Capital Healthcare Fin. Servs. v. Fall River Walk-in Emergency Med. Office, P.C., No. Civ. A. 02-11789-RCL, 2004 WL 40522, at * 1 (D. Mass. Jan. 7, 2004) (court disregarded 56.1 statement where party failed to reference "affidavits, depositions or other evidence in the record," but rather submitted a statement that was "rife with bald assertions entirely lacking in factual support."). Moreover, Plaintiffs' attempt to incorporate by reference citations in their Memorandum of Law should be rejected. Regardless, AstraZeneca's Counter Statement to Plaintiffs' L.R. 56.1 Statement ("AZ Counter Stmt.") sets forth the facts, with record citations, that correct and rebut Plaintiffs' mischaracterization of the record.

They also argue that AstraZeneca published and controlled AWPs, and improperly marketed the resulting "spread" between AWP and acquisition cost to physicians.[3] (Plaintiffs' L.R. 56.1 Statement of Undisputed Facts ("Pl. Rule 56.1") ¶¶ 4-7, 39-44.)

AstraZeneca did not "manipulate" the AWP for Zoladex, nor did it publish AWP; rather, AstraZeneca provided suggested AWPs for Zoladex to publishers prior to 2002 and those suggested AWPs were calculated consistently throughout the class period based on a well-known, industry-standard mark-up of 25% over the list price, or WAC, set by AstraZeneca, which was also provided to publishers. (See AZ Counter Stmt. ¶¶ 3-7, 42-43.) AstraZeneca also provided volume discounts from WAC to physicians who purchased Zoladex. (See AZ Counter Stmt. ¶¶ 42-43.) Such discounts are common practice in a competitive industry. (Id.) Moreover, it is well known that AWP does not include such discounts, does not reflect an actual average, and bears no predictable relationship to acquisition cost. (See AZ Counter Stmt. ¶¶ 41.)

More importantly, even if Plaintiffs' version of the facts was true and undisputed, neither Class 1 nor Class 2 would be entitled to summary judgment on their Chapter 93A claims. Indeed, Plaintiffs long recitation of the purported "facts" relating to AstraZeneca is nothing more than a sideshow intended to distract the Court from an inevitable conclusion: Plaintiffs have no claim unless their interpretation of AWP under the Medicare regulation and statute is correct, which, as discussed below, it is not.

[3] Although Plaintiffs' arguments and supposed "undisputed facts" are often stated in general terms, only two drugs are subject to the Court's January 30, 2006 class certification order: Zoladex and Pulmicort Respules. Even then, Plaintiffs have failed to support their motion with any facts relating to Pulmicort Respules. On this ground alone, summary judgment as to Pulmicort Respules must be denied.

ARGUMENT

Plaintiffs move for summary judgment against AstraZeneca on the Class 1 and Class 2 claims under Massachusetts Gen. Laws Ch. 93A, arguing that AstraZeneca's purported conduct in "manipulating," causing to be published and marketing an AWP for Zoladex that was not an "average sales price" was an "unfair" or "deceptive" practice, because the Medicare Part B regulation, and later the statute, required AWPs to "reflect actual costs in the marketplace or be at least reasonably related thereto." See Plaintiffs' Memorandum in Support of Motion for Partial Summary Judgment Against All Track 1 Defendants ("Pl. Mem.") at 41-46, 119-125. Indeed, Plaintiffs assert that the Medicare Part B regulation and statute placed AstraZeneca under a "legal duty" to include all relevant discounts in its AWP for Zoladex, because both the plain language of the term AWP and "recent official proclamations" purportedly demand such a result. (Pl. Mem. at 43-46). They further argue that the Class 1 and Class 2 Plaintiffs had "no control" over the amount of their Medicare Part B co-payments, and were therefore allegedly injured by the "simple action of making co-pays pursuant to a statutory directive." (Pl. Mem. at 124).

Plaintiffs' case therefore turns on the construction of the phrase "average wholesale price" and Plaintiffs have, at last, set forth the legal basis for their theory that the "statute" requires that "average wholesale price" be construed to mean "average sales price." As shown below, Plaintiffs' conclusion does not result from, and is contrary to, established principles of statutory construction. Accordingly, Plaintiffs' motion must be denied.

A. The Regulatory and Statutory Language

AWP first appeared in the context of Medicare reimbursement for drugs in 1991 when HCFA promulgated a regulation to implement statutory changes made by Congress in 1989. 42 C.F.R. § 405.517 (1992) (now superseded). The regulation provided for reimbursement "based

on the lower of the estimated acquisition cost *or* the national average wholesale price of the drug." 42 C.F.R. § 405.17 (emphasis added).

The Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4566 (a)(1997), established a new statutory requirement with respect to Medicare Part B covered drugs: it established as a matter of Federal law what "is" "the amount payable" to the "physician" who requests payments for a Medicare Part B covered drug. As codified in 42 U.S.C. § 1395u(o), entitled "Reimbursement for drugs and biologicals," the amendment provided in subsection (1) that "[i]f a physician's request for payment for services includes a charge for a [covered] drug or biological [other than on a cost or prospective payment basis], the amount payable for the drug or biological is equal to 95 percent of the average wholesale price."[4]

Neither the original regulation nor the 1997 legislation defined the phrase "average wholesale price."[5] Read without historical or other context – read sterilely as a component in a computation – the phrase is ambiguous. It is susceptible to different interpretations based on the point of sale (e.g., the average price offered or charged by wholesalers, or the average price offered or charged to wholesalers). It is silent as to how the "average" is to be computed in geographical terms (nationally, by state, by Standard Metropolitan Statistical Area, or otherwise), in temporal terms (annually, or more or less often), and in the "price" components to

[4] After this amendment established the statutory basis on which a "physician" had to be paid for Medicare Part B covered drugs, the Medicare Act allocated the responsibility for paying the "physicians' request for payment" of "95 percent of the average wholesale price." Section 1395l, entitled "Payment of Benefits," provided in subsection (a)(1)(S) that "there shall be paid from the Federal Supplemental Medical Insurance Trust Fund" in case of each individual participating in Medicare Part B "amounts equal to… (s) with respect to drugs and biologicals… the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in" Section 1395u(o)"– which was the statutory "95 percent of the average wholesale price." 42 U.S.C. § 1395u(o)(1). The beneficiary must pay the remaining 20% of the 95% of the Average Wholesale Price as a co-payment.

[5] There was no formal legislative history accompanying the Balanced Budget Act of 1997 – a conference report, a report from either House, an explanatory statement on the floor of either House by the sponsor – that explicitly explained the meaning of the statutory term "average wholesale price."

be "averaged." The statute is also silent as to who is to make those determinations of "average." The statute did not impose an obligation on non-governmental parties, such as wholesalers or manufacturers, either to report data to a governmental entity or to compute "averages."[6]

B. The Plaintiffs' Plain Language "Construction" of AWP

The Plaintiffs' heretofore unexplained theory why the phrase "average wholesale price" supposedly means, "by statute," the average sales price of Part B drugs is based on a flawed assumption, and supported by a de facto plea for this Court's conscious avoidance of the history and context of Medicare drug reimbursement.

Asking the Court only to read the words, "average" and "wholesale price," against dictionary definitions, (Pl. Mem. at 42), Plaintiffs argue that "wholesale price" is what a "retailer" pays for a product in expectation of "selling" it for a higher price to a "consumer." Plaintiffs silently assume the doctor "sells" the drug to the patient, then they announce that the "consumer" of Part B drugs was the patient of the doctor; the doctor, therefore, must be the "retailer." Plaintiffs argue that "average wholesale price" was intended to mean the "medial" (or "usual") cost of the product to the "retailer." Defendant drug manufacturers, Plaintiffs argue, sold Medicare Part B drugs to doctors/"retailers," and therefore they are "wholesalers." By this "reasoning," the statutory "average wholesale price" means the average price at which manufacturers/"wholesalers" sold drugs to the doctors/"retailers."

This argument is but a simplistic word game, dependent on a contrived "retailer" and "consumer" syllogism.[7] The argument assumes that the statutory phrase is composed of one

[6] In sharp contrast to this statute stand the provisions of the Medical Rebate Statute involving obligations to report "average manufacturer price" and "best price", *see* a 42 U.S.C. § 1396rs and imposing detailed obligations on drug manufacturers to calculate and to report in specified manner.

adjective ("average") and one compound noun ("wholesale price"). Why is Plaintiffs' silent assumption valid? It is not. A different result obtains when the phrase is parsed as one noun ("price") and two adjectives ("average" and "wholesale").[8] But importantly, however, Plaintiffs' word game is an attempted diversion from the obvious — these three words together constitute a known, widely (Plaintiffs say universally) used term with a specific meaning in the field of public and private drug reimbursement entirely different from what they suggest. See p. 9, infra.

Plaintiffs' proffered "statutory construction" would lead to a result Congress would find stupid – substantially increased costs to the Medicare system and co-payors for being treated with the same drugs. Beginning in 1998, with the effective date of the BBA amendments to the Medicare statute, doctors would, under Plaintiffs' view, be reimbursed 5% less than their out-of-pocket costs of the drugs, and doctors would receive nothing to cover the costs of staff, carrying inventory, and the like needed to administer drugs in their offices. Rather than participate in administering these drugs, every rational doctor would be expected to cease, thereby requiring that Part B drugs to be administered to Medicare beneficiaries in hospitals. Doing so would be

[7] The argument depends on the assumption that a doctor resells the drug to the patient/"consumer," the same way a car dealer exchanges a new car and title for cash with a buyer. A doctor who purchased a Medicare Part B drug provides health care services, including the range of skill from education and experience (e.g; diagnosis, interpreting test results, tracking treatments) and needed materials (from tongue depressors and examination gowns to injecting oncology drugs.). The doctor is compensated for providing those services.

[8] Definition in Black's Law Dictionary at 135, 1597(6th ed. 1990) of "average" ("in ordinary usage the term signifies the mean between two or more . . . numbers") and "wholesale" ("A sale in large quantity to one who intends to resell") result in "average wholesale price" meaning the "mean" prices of "large quantity" sales to resellers.

much more costly for Medicare, as the Court's expert observed.[9] Statutes should not be construed to produce unreasonable results that Congress would not have intended.[10]

Finally, Plaintiffs "statutory construction" argument requires this Court's conscious avoidance of all that the parties and the Court's own expert have amassed – the Court must ignore the entire historical, legislative, and regulatory histories of the precise subject.

C. The Intent of HCFA and then Congress in Directing that Physicians Be Reimbursed at the "Average Wholesale Price" Is Clear from the Context

For years this Court has been told what "AWP" is – AWP is what the three compendia publish as the average wholesale price. There may be disputes about the provenance, the propriety, or the significance of what the compendia publish as average wholesale price. But there is no dispute that the phrase refers to those published prices.

The "average wholesale prices" of drugs were published for many decades prior to the Medicare Part B statute and regulation. As the Court's own expert has explained, the pharmaceutical industry used the published "average wholesale price" as a pricing metric in large part because of the logistical necessities of pharmaceutical industry automation and

[9] The Court's independent expert explained the economic rationality to Medicare, as a system, of reimbursing physicians at published AWP, rather than their drug acquisition costs. Professor Ernst R. Berndt Report at 18-19, 50-51.

[10] E.g., Rowland v. California Men's Colony, 506 U.S. 194 (1993) (interpreting the meaning of the word "context" in 1 U.S.C. Sec. 1 in light of "the common mandate of statutory construction to avoid absurd results"); American Tobacco Co. v. Patterson, 456 U.S. 63, 71 (1982) ("Statutes should be interpreted to avoid untenable distinctions and unreasonable results whenever possible."); Perry v. Commerce Loan Co., 383 U.S. 392 (1966) ("When [the plain] meaning has led to absurd or futile results,… the court has looked beyond the words to the purpose of the act. Frequently, however, even when the plain meaning did not produce absurd results but merely an unreasonable one plainly at variance with the policy of the legislation as a whole the Supreme Court has followed that purpose, rather than the literal words.").

consolidation in the 1980s.[11] The "average wholesale price" is known and extensively used as a reference point for public and private drug reimbursement – that is Plaintiffs' mantra in this case.

Prior to 1998, HCFA instructed its carriers to use as the basis for reimbursement AWPs reported by industry publications, such as the Red Book, even though government reports at the time concluded that those AWPs substantially exceeded acquisition costs.[12] Even if one surmised that Congress was somehow unaware of the repeated OIG reports on the differences between the average wholesale price at which Medicare was reimbursing physicians and those physicians' acquisition costs,[13] Congress was repeatedly informed about "average wholesale price" by its own investigative arms (the General Accounting Office and the Congressional Budget Office), as the Court's own expert has summarized.[14] During hearings in connection with the 1997 legislation, both the Senate[15] and House[16] committees were specifically informed, again, of the "average wholesale price" and its use as a reference point in drug reimbursement calculations. The term "average wholesale price" was only used to refer to what was published.

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[11] Professor Ernst R. Berndt Report at 15-17.

[12] *See* 56 Fed. Reg. 25800 (June 5, 1991).

[13] These reports have been summarized in Attachment B to Professor Ernst R. Brendt's Report. *See also* Local Rule 56.1 Statement of Undisputed Material Facts In Support of Track 1 Defendants' Motion for Summary Judgment, March 15, 2006 ("Track 1 Rule 56.1") at ¶¶ 49, 59

[14] The Court's independent expert wrote, referring to reports by the Congressional Budget Office and the General Accounting Offices, "Hence, the fact that AWP should not be literally interpreted as an average price paid by pharmacies to wholesalers has long been widely publicized and communicated by various government organizations monitoring federal government reimbursements for prescription drugs. This has not been a secret." Professor Ernst R. Berndt Report at 37.

[15] *President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare: Hearings before the Committee on Finance, U.S. Sen.* 105th Cong. 85, 265 (1997) (statement by D. Shalala).

[16] H.R. Rep. No. 105-149 at 1354, 1398 (June 24, 1997) ("Medicare reimbursement for the top 10 oncology drugs ranges from 20% to 1000% per dosage more than acquisition costs.").

Congress then used the phrase "average whole price" in the legislation as the focal point for calculating reimbursement.

"Average wholesale price" is a long established, widely if not universally known and used term with a specific meaning: what the compendia publish as the average wholesale price. The phrase is a term of art in the pharmaceutical industry, specifically associated with drug reimbursement. Where a regulation or statute uses, but does not separately define, what is a recognized term of art in a field, courts presume Congress intended the term to have that same meaning.[17]

In construing statutes, courts must consider the broad context of the legislation, including not only the specific circumstances surrounding the enactment but also the prior legislative and

[17] See, e.g., Atlantic Mutual Insurance Co. v. Commissioner, 523 U.S. 382, 388 (1998) (in construing separately undefined statutory term "reserve strengthening" in taxing property and casualty injurers, Court first determines whether "reserve strengthening" has "an established meaning in the PC insurance industry"): Louisiana Public Service Commission v. FCC, 476 U.S. 355, 371-72 (1986) (holding that 'charges,' 'classifications' and 'practices' [as used in FCC regulation] are 'terms of art' which denote depreciation and accounting" and that they should therefore be "interpreted by reference to trade or industry to which they apply"); Corning Glass Works v. Brennan, 417 U.S. 188 (1974) (holding that paying night shift inspectors – all of whom were male – more than their daytime, female counterparts violates the Equal Pay Act's requirement that equal work, performed under "similar working conditions," receive equal pay. The Court found that the phrase is a term of art, noting "While a layman might well assume that time of day worked reflects one aspect of a job's "working conditions," the term has a different and much more specific meaning in the language of industrial relations."); McDermott International, Inc. v. Wilander, 498 U.S. 337 (1991) finding that ("seaman", which was not defined in the Jones Act, is a maritime term of art" and therefore that "[i]n the absence of contrary indication, we assume that when a statute uses such a term, Congress intended it to have its established meaning."); Morissette v. United States, 342 U.S. 246 (1952) ("[w]here Congress borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed."); O'Hara v. Luckenbach S.S. Co., 269 U.S. 364, 370 (1926), citing Unwin v. Hanson, L.R. 2 Q.B. 115, 119 (1891) ("the legislation deals with seamen and the merchant marine and, consequently, the phrase 'divided into… watches' is to be given the meaning which it had acquired in the language and usages of the trade to which the Act relates…"); Greenleaf v. Goodrich, 101 U.S. 278, 282, 284 (1880) ("the commercial designation of an article among traders and importers, where such designation is clearly established, fixes its character for the purpose of the tariff laws.").

regulatory histories, in order to construe the intent of Congress.[18] Ignoring those contexts, as Plaintiffs suggest, is not a judicial option.

The pieces of historical fact about "average wholesale price" and drug reimbursement, whether viewed broadly to include both Medicaid and Medicare, or limiting a view solely to Medicare Part B drug reimbursement, reveal the intent of HCFA and Congress in enacting the 1991 regulation and the 1997 legislation, respectively.[19] The published average wholesale price, a reference price that did not reflect various discounts, was used as a benchmark from which the Medicaid and, on its inception, the Medicare Part B programs reimbursed their respective providers.[20] HCFA, after many studies, publicly acknowledged that this benchmark price exceeded providers' costs, but explicitly reimbursed providers of Medicare Part B drugs at the

[18] See, e.g., Merrill, Lynch, Pierce, Fenner & Smith, Inc. v. Dabit 164 L. Ed. 2d 179 (U.S. 2006) (in construing intent of Congress in enacting SLUSA in 1998, Court examined 1934 Securities and Exchange Act, initial regulatory action and then divergent regulatory actions over decades prior to 1998 enactment); Wachovia Bank, N.A. v. Schmidt, 126 S. Ct. 941 (2006) (determining term "located" as used in construing the statute governing diversity citizenship for national banks based on a review of laws from 1882 to the present); Kelly v. Robinson, 479 U.S. 36 (1986) (holding that the Bankruptcy Code does not discharge criminal restitution orders, despite what the Court acknowledges is a plain reading of the statute, stating "In light of the strong interests of the States, the uniform construction of the old [bankruptcy] Act over three-quarters of a century, and the absence of any significant evidence that Congress intended to change the law in this area, we believe this result best effectuates the will of Congress."); Morissette v. United States, 342 U.S. 246 (1952) (reading a criminal intent requirement into a criminal conversion statute based on a finding that mal intent has always been a critical element of crimes, citing to sources as far back as a study of ancient Greece and the Bible, and interpreting the statute within the context of social welfare laws developed in the wake of the industrial revolution); Gilbert v. United States, 370 U.S. 650 (1962) (interpreting federal criminal forgery statute in light of common law forgery as it existed at time of predecessor statute's enactment).

[19] In stark contrast, the only support Plaintiffs cite for their construction of the statute is not legislative history, but by their own description, "recent official proclamations." (Pl. Mem. at 43). Specifically, Plaintiffs cite to the 2002 testimony of Thomas Scully, former Administrator of the Centers for Medicare & Medicaid. But this testimony, quoted out of context, was given well after the passage of the regulation and statute, and is not evidence of HCFA's or Congress's intent at the time of enactment. Similarly, the HHS-OIG Guidelines which Plaintiffs rely upon heavily, (Pl. Mem. 44-45), again quoted out of context, are not evidence of regulatory or congressional intent in enacting or implementing the regulation and statute; HHS-OIG has no authority to make or interpret rules or regulations. See Winters Ranch Partnership v. Viadero, 123 F.3d 327, 334 (5th Cir. 1997).

[20] *See* Track 1 Rule 56.1 at ¶¶ 20, 24, 47.

full price for policy reasons.[21] Over time, a new administration proposed a change, to reimburse providers of Medicare Part B drugs not on the basis of the published average wholesale price but on the basis of providers' costs for Part B drugs.[22] Congress enacted the 1997 legislation mandating doctors be paid 95% of the "average wholesale price."[23] HCFA directed that doctors be reimbursed on 95% of what the three compendia published as the average wholesale price for these drugs.[24] Congress prevented the agency from altering the basis for reimbursement until new legislation was enacted in 2003.[25]

Finally, assuming arguendo both that the meaning of the term "average wholesale price" was not established in the field and that the legislative history was not determinative, the result is controlled by the default rule of Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), which held that an agency's permissible interpretation of the statute it administers is binding on the courts.[26] In Chevron, the Supreme Court held that if a court determines that Congress had "not directly addressed the precise question at issue," and "the statute is silent or ambiguous with respect to the specific issue," id. at 843, the agency's interpretation is binding on the courts if it is one of various permissible interpretations.

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[21] *See* Track 1 Rule 56.1 at ¶¶ 10, 12, 23, 24, 35.

[22] *See* Track 1 Rule 56.1 at ¶¶ 50-51, 53-58

[23] *See* Balanced Budget Act of 1997 (BBA 97, P.L. 105-33).

[24] *See* Track 1 Rule 56.1 at ¶¶ 47, 52, 61.

[25] *See* Track 1 Rule 56.1 at ¶¶ 89.

[26] Moreover, as demonstrated in the Track 1 Defendants' Memorandum of Law in Support of Joint Motion for Summary Judgment, at 9-12, HCFA's interpretation of its own regulation, which clearly did not equate AWP with ASP from 1992 through 1998, is entitled to even more deferential review than under Chevron. See Visiting Nurse Ass'n of N. Shore, Inc. v. Bullen, 93 F.3d 997, 1002 (1st Cir. 1996) (quoting Nat'l Med. Enters. v. Shalala, 43 F.3d 691, 697 (D.C. Cir. 1995)).

> "In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." Id. at 844.

The Chevron analysis is especially controlling in complex and technical programs like Medicare. Thomas Jefferson University v. Shalala, 512 U.S. 504, 512 (1994). See also Strickland v. Maine Department of Human Services, 48 F.3d 12 (1st Cir. 1995) (statutory word "cost", not defined in statute, ambiguous as to whether a subtraction for depreciation is required; agency determination binding under Chevron); Harris v. Olszewski, No. 04-2479, 2006 U.S. App. LEXIS 6894 (6th Cir., Mar. 21, 2006) (statutory phrase "medical devices" in Medicaid Act ambiguous as to whether incontinence products are included; approval of a state Medicaid contract including incontinence products as "medical devices" is a Chevron determination binding on courts).

After enactment of the Balanced Budget Act of 1997, HCFA interpreted the statutory term to mean the "national average wholesale price." 63 Fed. Reg. 58814, 58849 (Nov. 2, 1998). HCFA then interpreted the statutory term to mean, and directed payors to reimburse physicians 95% of, "the AWP as reflected in services such as the Red Book, Blue Book, or Medispan." HCFA Pub. 60 AB, Transmittal No. AB-98-76 (Dec 1, 1998) (emphasis supplied).[27]

HCFA has consistently interpreted the statutory term "average wholesale price" to mean what was "reflected" as AWP "in" those publications. That interpretation is certainly a permissible one under Chevron, and is binding on the courts. Accordingly, Plaintiffs' attempt to

[27] In providing notice, HCFA acknowledged, again, as it had said so many times in the past, that published AWP exceeded actual providers' actual acquisition costs for covered drugs: "From a series of OIG reports spanning the past 10 years, it is clear that the AWP is higher than the amount typically paid for drugs by physicians who bill the program." 63 Fed. Reg. 58814, 58849 (Nov. 2, 1998). Nevertheless, HCFA determined by this that physicians would be reimbursed at 95% of the published AWP, which was substantially higher than their actual acquisition costs.

manufacture a construction of AWP that equals ASP, or a number reasonably related thereto, fails as a matter of law.

CONCLUSION

For all of the above reasons, the Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants should be denied.

Dated: Boston, Massachusetts
April 7, 2006

Respectfully Submitted,

By: /s/ Lucy Fowler

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on April 7, 2006, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Lucy Fowler
Lucy Fowler